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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,862	09/24/2003	Michael T. Barrett	10021287-1	5754

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,862	BARRETT ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-40* is/are pending in the application.

4a) Of the above claim(s) *22-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-21 and 35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed 1/17/2007. Currently Claims 1-9, 11-40 are pending. Claim 10 has been canceled. Claims 22-34 are withdrawn as being drawn to a nonelected invention.

2. A complete reply to the final rejection must include cancellation of nonelected claims and subject matter or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. The following rejections to Claims 1-9, 11-21, and 35-40 are reiterated. Response to arguments follows.

4. This action is FINAL.

Withdrawn Objections

5. The objection to the claims made in section 4 of the previous office action is moot based on amendments to the claims.

Withdrawn Rejections

6. The rejection of Claims 1-2 made under 35 USC 101 made in section 5 of the previous office action is moot based on amendments to the claims.

7. The rejections of Claims 11-21 made under 35 USC 112 made in section 6 of the previous office action is moot based on amendments to the claims.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-21, and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al. (US Patent Application 09/976423 August 15, 2002).

With regard to Claim 1, Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (p. 2 paragraph 15). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102). Hogan et al. teaches the profile includes unique genomic identifier (non coding SNPs) to provide a secure accurate internal reference for archiving and tracking genetic data specific to the particular subject (p. 12

paragraph 134). Therefore, the internal reference of the non-coding SNPs placed on the genomic profile is used to identify the source (i.e. identify the subject of the profile).

With regard to Claim 3, Hogan et al. teaches that sample can be from human blood or cultures, which would be considered clinical samples (p. 10 paragraph 111).

With regard to Claim 4, Hogan et al. teaches screening the sample for analytes of clinical relevance such as screened for abnormal B1 adrenergic receptor response (p. 12 paragraph 129).

With regard to Claim 5, Hogan et al. teaches that the profile can be made during the perioperative period wherein the sample would be screened for the presence of the perioperative factors (p. 14 paragraph 150). With regard to Claims 6-7, Hogan et al. teaches the profile can be generated from the subject at the time of birth to be store and later screened when the subject is planning surgery (p. 16 paragraph 186).

With regard to Claim 8, test samples are analyzed for the presence of target DNA molecules using a DNA chip (p. 15 paragraph 173). With regard to Claim 9, Hogan et al. teaches the profile can be generated using a DNA chip hybridization assay (p. 5 paragraph 168).

Claim 10 is drawn to a method comprising assaying a sample for an analyte if the identified SNP profile matches a predetermined source. With regard to Claim 10, Hogan et al. teaches that the SNP profile is tailored to include markers for specific surgical procedures (p. 12 paragraph 132). Therefore a patient is assayed for the presence of particular analytes if the SNP profile matches a patient (source), which is planning a specific surgery such as cardiac or brain surgery (p. 10 paragraph 113).

With regard to Claim 11, Hogan et al. screens a sample (perioperative subject) for at least one analyte (marker for defects for surgery) and determines a SNP profile (generates a genomic profile of patient). (p. 1 paragraph 12, p. 2 paragraph 15, p. 3 paragraph 34 and p. 9 paragraph 102). Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (determining a SNP profile) (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (screening for analytes) (p. 2 paragraph 15). Hogan et al. teaches screening the sample for analytes for surgery, such as, markers for defects in metabolism, malignant hyperthermia, and sepsis (analytes) (p. 3 paragraph 34). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102).

With regard to Claim 12, test samples are analyzed for the presence of target DNA molecules using a DNA chip (p. 15 paragraph 173).

With regard to Claims 13-14, Hogan et al. teaches the profile can be generated from the subject at the time of birth to be store and later screened when the subject is planning surgery (p. 16 paragraph 186). With regard to Claim 15, Hogan et al. teaches that the profile can be made during the perioperative period wherein the sample would be screened for the presence of the perioperative factors (p. 14 paragraph 150).

With regard to Claim 16, Hogan et al. teaches the profile can be generated using a DNA chip hybridization assay (p. 5 paragraph 168).

With regard to Claim 17, Hogan et al. teaches a method of genomic screening to determine if a subject is suitable for medical or surgical treatment (evaluating a subject for a condition) (Abstract). With regard to Claim 18, Hogan et al. teaches a method of screening for co-existing diseases (p. 2 paragraph 13).

With regard to Claim 19, Hogan et al. teaches a method of genomic profile comprising a presymptomatic diagnosis (p. 2 paragraph 13).

With regard to Claim 20, Hogan et al. teaches s method of screening a genomic profile for genetic markers to determine an operative course of action (p. 1 and 2 paragraph 12). Hogan et al. teaches that some markers are related to certain conditions such as defects in metabolism, malignant hyperthermia, and sepsis (p. 3 paragraph 34). Hogan et al., therefore, teaches screening a patient for conditions and therefore monitors a subject.

With regard to Claim 21, Hogan et al. teaches a method in which the sample (subject) is human (p. 10 paragraph 111).

With regard to Claims 35-36, Hogan et al. teaches an array based screening method of determining the condition of a patient for surgery (Abstract). Hogan et al. teaches the profile includes unique gnomic identifier (non coding SNPs) to provide a secure accurate internal referent for archiving and tracking genetic data specific to the particular subject (p. 12 paragraph 134).

With regard to Claim 37, Hogan et al. teaches a method of using an array, which contains SNPs both as identifier of the subject and as markers for disease and conditions associated with surgery (p. 1 and 2 paragraph 12, p. 3 paragraph 34, p. 15

paragraph 173, and p. 12 paragraph 134). Hogan et al. teaches a method of determining a SNP profile based on the pattern of hybridization, which is detected on the array (detecting binding complexes on surface of the array) (p. 15 paragraph 170).

With regard to Claim 38, Hogan et al. teaches a method of taking a sample to a genomic profiling lab and generating raw data (first location), then producing the genomic profile suitable for interpretation by a treating clinician and sending it to the clinician (second location) (p. 17 paragraph 189 and 190). With regard to Claim 39, Hogan et al. teaches the second location can be away from the lab facility and that the data can be provided electronically to the clinician (p. 17 paragraph 192). Therefore the second location is remote from the first location. With regard to Claim 40, Hogan et al. teaches preparing the raw sequence data into a form suitable for interpretation by a treating clinician such as a report that be printed or displayed on a computer monitor (p. 17 paragraph 190).

Response to Arguments

The reply traverses the rejections. A) The reply assert that Hogan et al. does not disclose using a genomic profile to determine if the SNP profile matches a predetermined source or assays a sample from the subject for the presence of at least one analyte (p. 13 3rd paragraph). B) The reply asserts Hogan is either used to screen a sample for a given polymorphisms that is indicative of a subject's risk of anesthesia related complications or it is used to track genetic data specific to the subject but that Hogan et al. does not disclose generating a SNP profile to determine the source of the

sample if the SNP profile matches a predetermined source than assaying the sample (p. 13 3rd paragraph).

These arguments have been thoroughly reviewed but have not been found persuasive.

A) As discussed in the argument set forth above, Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (p. 2 paragraph 15). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102). Hogan et al. teaches the profile includes unique genomic identifier (non coding SNPs) to provide a secure accurate internal reference for archiving and tracking genetic data specific to the particular subject (p. 12 paragraph 134). Therefore, the internal reference of the non-coding SNPs placed on the genomic profile is used to identify the source (i.e. identify the subject of the profile). Therefore, Hogan et al. teaches a SNP profile with an internal reference of SNPs, which are assayed to determine if the sample matches a predetermined source (i.e. the perioperative patient).

B) As stated above, Hogan et al. teaches a method of a SNP profile, which has SNP information of r risk of anesthesia and SNP specific genetic data to track a subject. This SNP profile therefore has a section, which matches the SNP profile to a predetermined source (i.e. the perioperative patient). Hogan et al. teaches that the SNP profile is tailored to include markers for specific surgical procedures (p. 12 paragraph

132). Therefore a patient is assayed for the presence of particular analytes if the SNP profile matches a patient (source), which is planning a specific surgery such as cardiac or brain surgery (p. 10 paragraph 113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al. (US Patent Application 09/976423 August 15, 2002) in view of Hunter et al. (US Patent Application 09/822635 November 8, 2001).

Hogan et al. teaches a method of providing a sample from a perioperative subject and generating a genomic profile (p. 1 paragraph 12). Hogan et al. teaches identifying the sample on the basis of the profile to determine the course of action during and after surgery (p. 2 paragraph 15). Hogan et al. teaches screening the sample for analytes for surgery, such as, markers for defects in metabolism, malignant hyperthermia, and sepsis (p. 3 paragraph 34). Hogan et al. teaches a genomic profile refers to a set of information such as the presence or absence of a specific set of SNPs (p. 9 paragraph 102).

Hogan et al., however, does not teach comparing the SNP profile to a reference profile.

Hunter et al. teaches a method of evaluating a subject by comparing the subject expression profile to one or more reference profiles (p. 29 paragraph 357).

Therefore it would have been prime facie obvious to one of ordinary skill in the art to modify the method of Hogan et al. to include a method step of comparing the SNP profile to a SNP reference profile as taught by Hunter et al. The ordinary artisan would be motivated to modify the method of Hogan et al. to include a method step of comparing the SNP profile to a SNP reference profile as taught by Hunter et al., because Hunter et al. teaches a method of using reference profiles to evaluate a subject to determine if the subject is similar a normal target (p 25-26 paragraph 300). The

ordinary artisan would be motivated to compare the SNP profile of a patient as taught by Hogan et al. to a control reference sample in order to determine if the patient had the mutational or wild type marker for specific diseases and conditions associated with surgery progression.

Response to Arguments

The reply traverses the rejection. The reply asserts that Hogan et al. does not teach identifying a SNP profile to a predetermined source (p. 11 3rd paragraph). The reply asserts that Hunter et al. only teaches comparing expression levels of a test compound, but Hunter et al. does not compare SNP profiles (p. 12 1st paragraph).

These arguments have been thoroughly reviewed but have not been found persuasive.

The combination of Hogan et al. and Hunter et al. provide the limitations to the claim. Hogan et al., as discussed in the arguments presented above, teaches identifying SNP profiles to a predetermined source. However, Hogan et al. does not teach comparing the SNP profile to a reference profile. Hunter et al. provides the method steps and the motivation to compare a SNP profile to a reference, because as taught by Hunter et al. using reference profiles allows one to evaluate a subject to determine if the subject is similar to a normal target (p. 25-26 paragraph 300) thereby allowing the ordinary artisan to determine if a patient had mutational or wild type markers for specific disease and conditions associated with surgery progression.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

CARLA J. MYERS
PRIMARY EXAMINER